DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Haemonetics Corporation
Attention: Mr. Brian Ciccariello
400 Wood Road
Briantree, MA 02184

Re: BK150287

Trade/Device Name:	Haemonetics MCS + 8150 Apheresis System
Regulation Number:	21 CFR 864.9245
Regulation Name:	Automated blood cell separator
Regulatory Class:	Class II
Product Code:	GKT
Dated:	July 22, 2015
Received:	July 23, 2015

Dear Mr. Ciccariello:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

If you have any questions concerning the contents of the letter, please contact Beth Walton at (240) 402-8446 or beth.walton@fda.hhs.gov.

Sincerely,

Richard J. Davey, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosure
Indications for Use

Indications for Use

510(k) Number: BK150287

Device Name: Haemonetics MCS+ 8150 Apheresis System

The MCS+ 8150 device may be used to collect the following blood components from allogeneic and autologous donors.

- Two units of Red Blood Cells collected and stored in CP2D/AS-3. (832 disposable set) *Two Unit Red Blood Cell Protocol.*
- One unit of Red Blood Cells collected and stored in CP2D/AS-3 and one unit of plasma. (822 and 822-2P disposable sets) *Red Blood Cells and Plasma Protocol.*
- Two units of Red Blood Cells, Leukocytes Reduced, collected and stored in CP2D/AS-3. (832F disposable set) *Two Unit Red Blood Cell Protocol* Filtration must be done within 8 hours of phlebotomy if the Red Blood Cells are at room temperature or within 72 hours of phlebotomy if the Red Blood Cells are stored at 1-6°C.
- One unit of Red Blood Cells, Leukocytes Reduced, collected and stored in CP2D/AS-3, and plasma. (822F-2P disposable set) *Filtered Red Blood Cell and Plasma Protocol.* Filtration must be between 6-72 hours post phlebotomy on cells that have been stored at 1-6°C.

Plasma collected using the 822, 822-2P, and 822F-2P disposable sets may be:

- Fresh Frozen Plasma
  - *Must be prepared and placed in a freezer at -18°C or colder within 8 hours of phlebotomy.*
- Source plasma
- Plasma frozen within 24 hours after phlebotomy (PF24)
  - *Must be stored at 1-6°C within 8 hours of phlebotomy and placed in a freezer at 18°C or colder within 24 hours after phlebotomy.*
  - *Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.*

One unit of CP2D/AS-3 Red Blood Cells may be collected from allogeneic donors in the event of a terminated procedure after the first draw cycle ends. (832 & 832F disposable set).

Prescription Use__X__	AND/OR	Over-The-Counter Use__
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CBER, Office of Blood Research and Review

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Division Sign-Off
Office of Blood Research and Review